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REMARKS

This Amendment is in response to the Office Action dated April 21, 2006. As set forth in the Office Action Summary, claims 1-61 are pending in the application. Claims 2-5, 9, 13-45, 47 and 48 are withdrawn and claims 1, 6-8, 10-12, 46 and 49-61 are listed as rejected. Claim 7 was amended to correct informalities noted in the claim. No new matter was added. Reconsideration of the claims is requested.

**I. The Office Action fails to set forth a substantive rejection for claim 61**

Although claim 61 is listed as rejected in the Office Action Summary, the Office Action contains no substantive rejection of claim 61. Pursuant to MPEP § 707, where a claim is rejected, the grounds for the rejection must be clearly stated. The Office Action fails to recite a statutory basis or reason for rejection of claim 61 and thus, allowance of claim 61 is respectfully requested since the Office Action fails to recite a *prima facie* basis to reject claim 61.

**II. Response to Claim Rejections – 35 U.S.C. § 103**

Claims 1, 6-8, 10-12, 46 and 49-60 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jansen 6,528,006 in view of Yamane et al, U.S. Patent No. 5,875,004.

Claim 1 and dependent claims 6-8, 10-12 and 50 recite *inter alia* at least partially cutting a material segment with a beam wherein a path of the beam is controlled by a process control unit . . . based upon a pattern determined by comparing the material segment to a target image. Claims 1, 6-8, 10-12, 46 and 49-60 were rejected on the basis that Jansen teaches “where the laser is programmed to cut only to a particular depth (col. 2, lines 20-40) via the path of the beam” (col. 2, lines 40-60). Jansen discloses separation along a pre-determined contour or ablation in an area-wise manner to achieve a desired thickness dimension. In Jansen, “instantaneous thickness is measured pointwise and stored.” The stored values are utilized to generate setting parameters for the laser, such as energy density, pulse rate and effective duration. As properly interpreted, claims 1, 6-8, 10-12, 46 and 49-60 include controlling the path of the

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beam based upon a pattern determined by comparing the material segment to a target image, not controlling depth or laser energy, density, pulse rate and duration along the path of the laser beam.

Col. 2, lines 19-40 of Jansen referenced above read as follows.

...synthetic resin foil is separated by means of a laser beam bundle along the predetermined contour and/or is subjected to ablation in an area-wise manner until the respective desired thickness dimension is obtained.

Surprisingly, it has been found that the area-wise ablation and separation can be carried out reproducibly with the requisite precision while the synthetic resin surface is locally melted at respective laser burn spots and the melted material vaporized. The differences in the separation and area-wise ablation by means of a laser lies only in the penetration depth or machining depth, whereby the separation or cutout of the desired synthetic resin foil contour is effected by forming a groove with growing depth. The laser and the optics association therewith form a machining tool which does not come into contact with the workpieces so that no wear is generated. Via corresponding servomotors, exact guidance of the laser beam bundle is possible. The process of the invention thereby has the advantage that, from the viewpoint of the synthetic resin foil thickness dimension as produced by injection, dip casting or spraying, there are no requirements from the point of view of the desired thickness distribution since the foil can be directly subjected to a material removal process.

Thus, Jansen does not teach or suggest controlling a path of a beam by a process control unit to cut based upon a pattern as recited in the claims. In fact, on page 5 of the Office Action, the Examiner admits that Jansen does not teach "controlling the path of the beam based upon a pattern determined by comparing the material segment to a target image".

The Office Action states that although Jansen does not teach controlling a path of the beam based upon a pattern determined by comparing a material segment to a target image, Yamane teaches a process control unit to compare the workpiece to correspond to a target image in col. 2, line 40-col. 4, line 25. Although col. 2, line 40- col. 4, line 25 of Yamane disclose comparing a workpiece to a target image, neither Yamane (e.g. col. 2, line 40 – col. 4, line 25) nor Jansen as admitted teach wherein a path of a beam is controlled by a process control unit to

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cut the material segment based upon a pattern determined by comparing a material segment to a target image.

Jansen in combination with Yamane teach inspection of a plastic film relative to a target image and not the recited claim elements of controlling a path of a beam by a process control unit to cut based upon a pattern determined by comparing the material segment to a target image. The combination teaches separating or ablating a material segment with a beam relative to a setpoint thickness distribution as taught by Jansen and a processor to compare a material segment to a target image as taught by Yamane. The combination fails to teach each of the claim elements including controlling a path of a beam using a process control unit to cut based upon a pattern determined by comparing a material segment to a target image. Since the combination fails to teach each of the recited claim elements, the Office Action fails to establish a *prima facie* basis to reject claims 1, 6-8, 10-12, 46 and 49-60.

Claim 46 recites a method to remove portions of a tissue sheet having different thicknesses comprising imaging the tissue sheet on a smooth surface to evaluate the thickness of the tissue sheet at different points, and cutting the tissue sheet to separate portions of the tissue sheet with a thickness outside of a selected range. Claim 46 was rejected on the basis that Jansen teaches a method for cutting a material segment where the target is a pericardial patch or chordae in col. 4, lines 15-65 and col. 1, lines 10-55. Col. 4, lines 15-65 and col. 1, lines 10-55 of Jansen do not teach a tissue sheet.

Appropriate bioprosthetic tissue materials can be formed from natural materials, synthetic tissue matrices and combinations thereof. Applicant's Specification, ¶[0056], Publication No. US2002/0091441. As set forth in ¶[0056] of Applicant's specification, synthetic tissue matrices can be formed from extracellular matrix proteins that are crosslinked to form a tissue matrix or from synthetic materials, such as polymers, that have or have had viable cells associated with the matrix. Thus tissue materials have viable cells or structures formed from viable cells that are no longer present.

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Jansen discloses separation or ablation of synthetic resin foils or plastic film, not a tissue sheet. See Col. 1, lines 14-20, abstract, col. 2, line 22. Thus, the Office Action fails to establish a *prima facie* basis to reject claims 46, 49 and 51-60.

Jansen teaches separation and/or ablation in an area-wise manner to achieve a desired thickness, but not separation of portions with a thickness outside of a selected range. As disclosed in Jansen, thickness measurements are used to determine thickness variations from place to place to ascertain the degree that a surface is ablated at different places. The process ablates the material to a desired thickness, but there is no separation of portions outside of a selected thickness.

Dependent claims 6-8, 10-12, and 49-61, which are dependent from independent claims 1 and 46, were also rejected. While Applicant does not acquiesce with the particular rejections to these dependent claims, it is believed that these rejections are moot in view of the remarks made in connection with independent claims 1 and 46. These dependent claims include all of the limitations of the base claim and any intervening claims and recite additional features which further distinguish these claims from the cited references.

Applicant respectfully requests withdrawal of the rejection of claims 1, 6-8, 10-12, 46, and 49-61 under 35 U.S.C. § 103(a) as being unpatentable over Jansen in view of Yamane et al. Based upon the foregoing, allowance of claims 1, 6-8, 10-12, 46 and 49-61 is respectfully requested.

The Director is authorized to charge any fee deficiency required by this paper or credit any overpayment to Deposit Account No. 23-1123.

Respectfully submitted,

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